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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/603,094

06/25/2003

Don J. Diamond

1954-410

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7590

02/05/2009

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WASHINGTON, DC 20005

EXAMINER

HUMPHREY, LOUISE WANG ZHIYING

ART UNIT

PAPER NUMBER

1648

NOTIFICATION DATE

DELIVERY MODE

02/05/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/603,094	<b>Applicant(s)</b> DIAMOND, DON J.	
	<b>Examiner</b> LOUISE HUMPHREY	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2008 and 18 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 3,4 and 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 November 2008 has been entered.

**DETAILED ACTION**

This Office Action is in response to the amendment filed on 18 July 2008. Claims 1-14 are pending. Claims 3, 4 and 12-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b). Claims 1, 2 and 5-11 are currently examined.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2 and 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a "fusion peptide composed of a T helper epitope fused to a CMV CTL," which renders the claim limitation unclear. The term "CTL" stands for cytotoxic T

lymphocyte, which is a cytotoxic T cell, not a peptide. Applicant may consider amending the claim to read "a T helper epitope fused to a CMV CTL epitope."

Claims 2 and 5-11 are rejected for depending from claim 1.

***Affidavit or Declaration under 37 CFR 1.132***

The affidavit under 37 CFR 1.132 filed on 18 July 2008 is sufficient to overcome the rejection of claims 1, 2, 5, 6 and 9-11 based upon the BenMohamed reference (May 2002, No. O in IDS filed 08 March 2004).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The rejection of claims 1, 2, 5, 6 and 9-11 under 35 U.S.C. §102(a) as being anticipated by BenMohamed et al. (May 2002, No. Q in IDS filed 08 March 2004, hereinafter "BenMohamed") is **withdrawn** in response to Applicant's amendment.

Applicant's arguments with respect to claims 1, 2, 5, 6 and 9-11 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5, 6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prieur *et al.* (1998, WO 98/26074, No. F in IDS filed 08 March 2004, hereinafter "Prieur") in view of Livingston *et al.* (1999, No. YY in IDS filed 08 March 2004, hereinafter "Livingston").

The instant claims are directed to an unlipidated cytomegalovirus (CMV) vaccine comprising a fusion protein comprising a T helper epitope, PADRE, fused to a CMV CTL epitope pp65 (residues 495-503) identified by SEQ ID NO:1, which is a nonameric peptide of the sequence NLVPMVATV.

Prieur discloses a vaccine or a pharmaceutical composition comprising a fusion protein comprising cytomegalovirus (CMV) CTL epitope, a HLA-DR restricted peptide (Abstract and Claims), NLVPMVATV (Figure 4), which matches the claimed SEQ ID NO:1, corresponding to amino acids 495 to 503 of CMV protein pp65.

Prieur does not disclose the fusion partner of a T helper epitope.

Livingston discloses a fusion peptide containing a PADRE epitope fused to a CTL epitope (page 3088, right column, 2nd full ¶; page 3089, left column, Material and Methods).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Prieur's CMV fusion peptide vaccine by fusing the HCMV pp65 CTL epitope to a PADRE as suggested by Livingston. The skilled artisan would have been motivated to do so to enhance the amount immune response elicited by the HCMV pp65 CTL epitope. There would have been a reasonable expectation of success, given the disclosure that PADRE peptides support the induction and expansion of virus-specific CTL and B cells because the T helper epitopes induce T helper responses that overcome CTL tolerance against specific epitopes, as taught by Livingston. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1, 2 and 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prieur *et al.* (1998, WO 98/26074, hereinafter "Prieur") in view of Livingston *et al.* (1999, No. YY in IDS filed 08 March 2004, hereinafter "Livingston") and Krieg *et al.* (WO 1212972, 30 April 2001, hereinafter "Krieg").

The instant claims are directed to an unlipidated cytomegalovirus (CMV) vaccine comprising a fusion protein comprising a T helper epitope, PADRE, fused to a CMV CTL epitope pp65 (residues 495-503) identified by SEQ ID NO:1, which is a nonameric peptide of the sequence NLVPMVATV, and further comprising a DNA adjuvant.

The disclosure of Prieur and Livingston is set forth above. Neither Prieur nor Livingston discloses a DNA adjuvant.

Krieg describes immunostimulatory nucleic acids. Specifically, Krieg discloses the instantly claimed DNA adjuvant of SEQ ID NO:10. See page 57, SEQID NO:959, in Table A.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the unlipidated CMV pp65<sub>495-503</sub>-PADRE fusion peptide vaccine by adding a DNA adjuvant as taught by Krieg as routine optimization of a vaccine. The skilled artisan would have been motivated to do so to enhance the amount of immune response elicited by the nonameric CMV pp65 CTL epitope. There would have been a reasonable expectation of success, given that these DNA adjuvants preferentially activate non-rodent immune cells such as B cells, natural killer cells and monocytes, as taught by Krieg. Thus, the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. H./  
Examiner, Art Unit 1648

/Jeffrey S. Parkin/  
Primary Examiner, Art Unit 1648

28 January 2009